

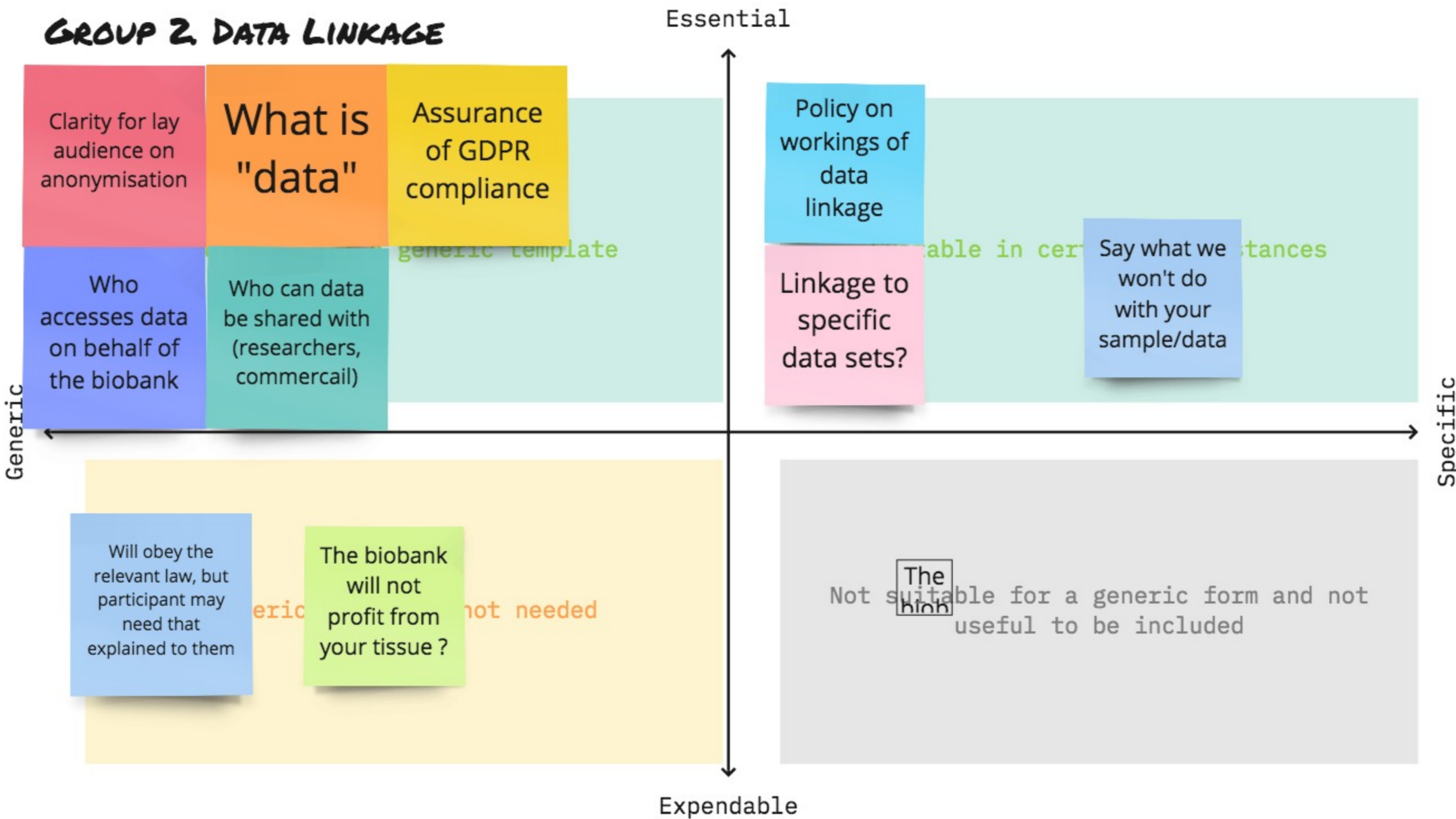
Developing Consensus on Access Documentation

The purpose of this breakout discussion was to compare examples of access documentation from a range of biobanks.

Participants were then tasked to chart wording based on how essential it is to have in the documentation, and where it should sit on the generic to specific / essential to expendable spectrum.



GROUP 2. DATA LINKAGE



Essential

Clarity for lay audience on anonymisation

What is "data"

Assurance of GDPR compliance

Policy on workings of data linkage

Linkage to specific data sets?

Say what we won't do with your sample/data

Who accesses data on behalf of the biobank

Who can data be shared with (researchers, commercail)

Will obey the relevant law, but participant may need that explained to them

The biobank will not profit from your tissue?

The high
Not suitable for a generic form and not useful to be included

Expendable

Generic

Specific

GROUP 1: COMMERCIAL ACCESS

Essential

If yes, EQUITABLE commercial access fundamental point -
Access to researchers (commercial, hospital, academic)
GOOD research
for PUBLIC benefit

Will there be a charge - and if so, why?

Samples are data - appropriate contract then when transferring
access document and MTAs.

Sample may leave the country

Use of positive language - not commercial gain/exploitation but commercial use or
involvement for benefit of public/patient groups.

Animal research may or may not be involved

Provide FAQs?

Protect identity - could the full scope of this be stated as an option though where this is a possibility? As a tiered consent
- or further information go to website.

Suitable for a generic template

Suitable in certain circumstances

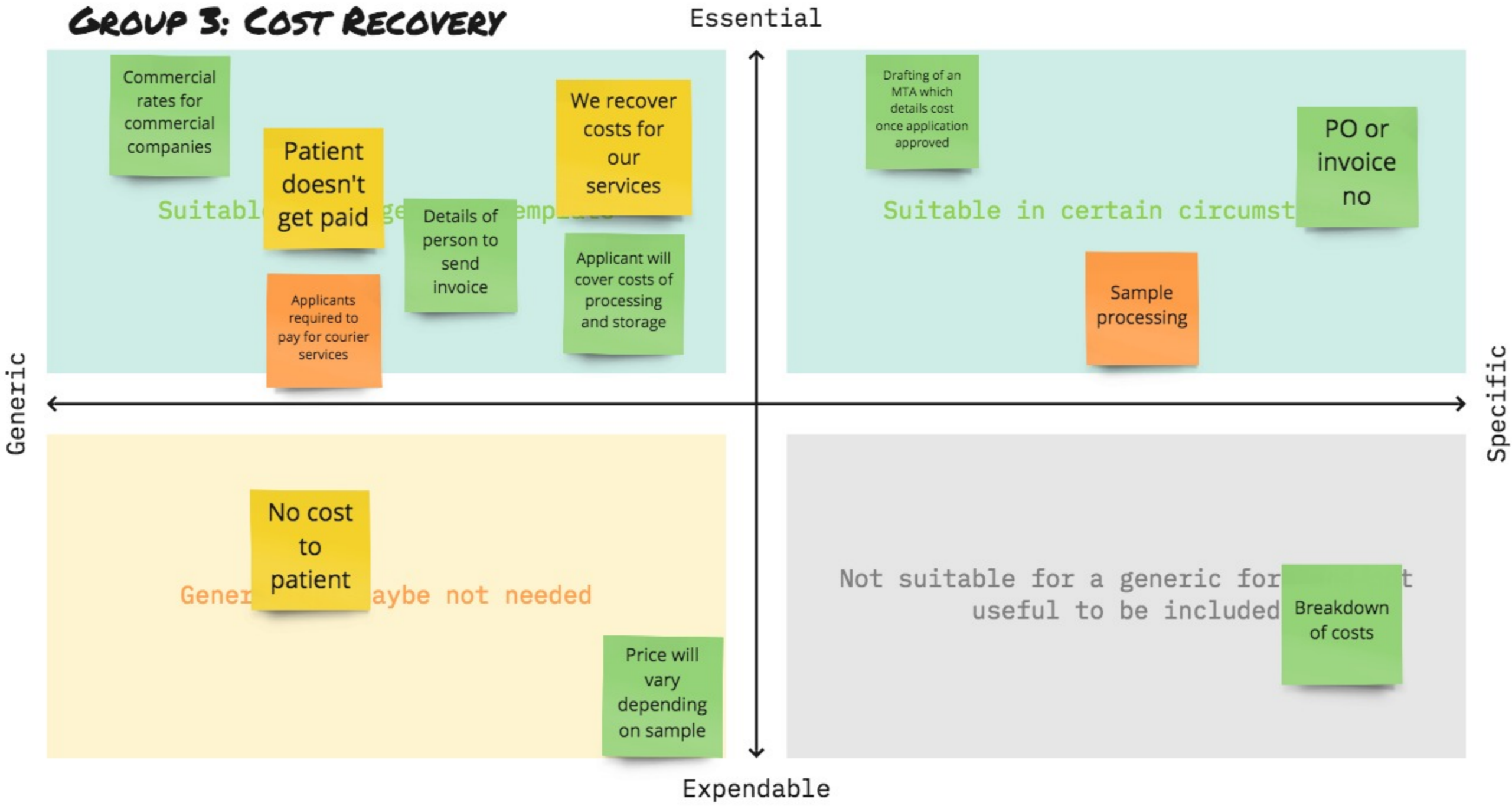
Specific

Generic but maybe not needed

Not suitable for a generic form and not
useful to be included

Expendable

GROUP 3: COST RECOVERY



GROUP 6: SUPPLYING DATA

Essential

Generic ← → **Specific**

Info for animal use as a possibility

PIS: No research return to patients

PIS: class... whether or not results is fed back

Access form+ MTA: One sentence specifically to acknowledge use of samples from biobank

Consent form: feedback results to patients via GP

PIS: research updates rather than individual feedback of results

form + MTA: Wales bank have a DOI to link to the bank in publications. DOI is cited in publications resulting from samples used from the bank

GROUP 7: RESEARCH RETURN

Essential

Suitable in certain circumstances

Consent form + PIS: patients made aware and asked whether they are happy for data to be shared in countries that have less stringent measures than the UK

Access Form: data sharing back to the biobank

Consent form: Clinically accredited labs only

Specific

Generic ← → **Specific**

maybe not needed

generic form and not be included

Expendable

Not suitable for a generic form and not useful to be included

Access form+ MTA: Listing Biobanks as authors

traceability issues with the data and IP associated with it

Logistics surrounding data return to biobank is too complicated

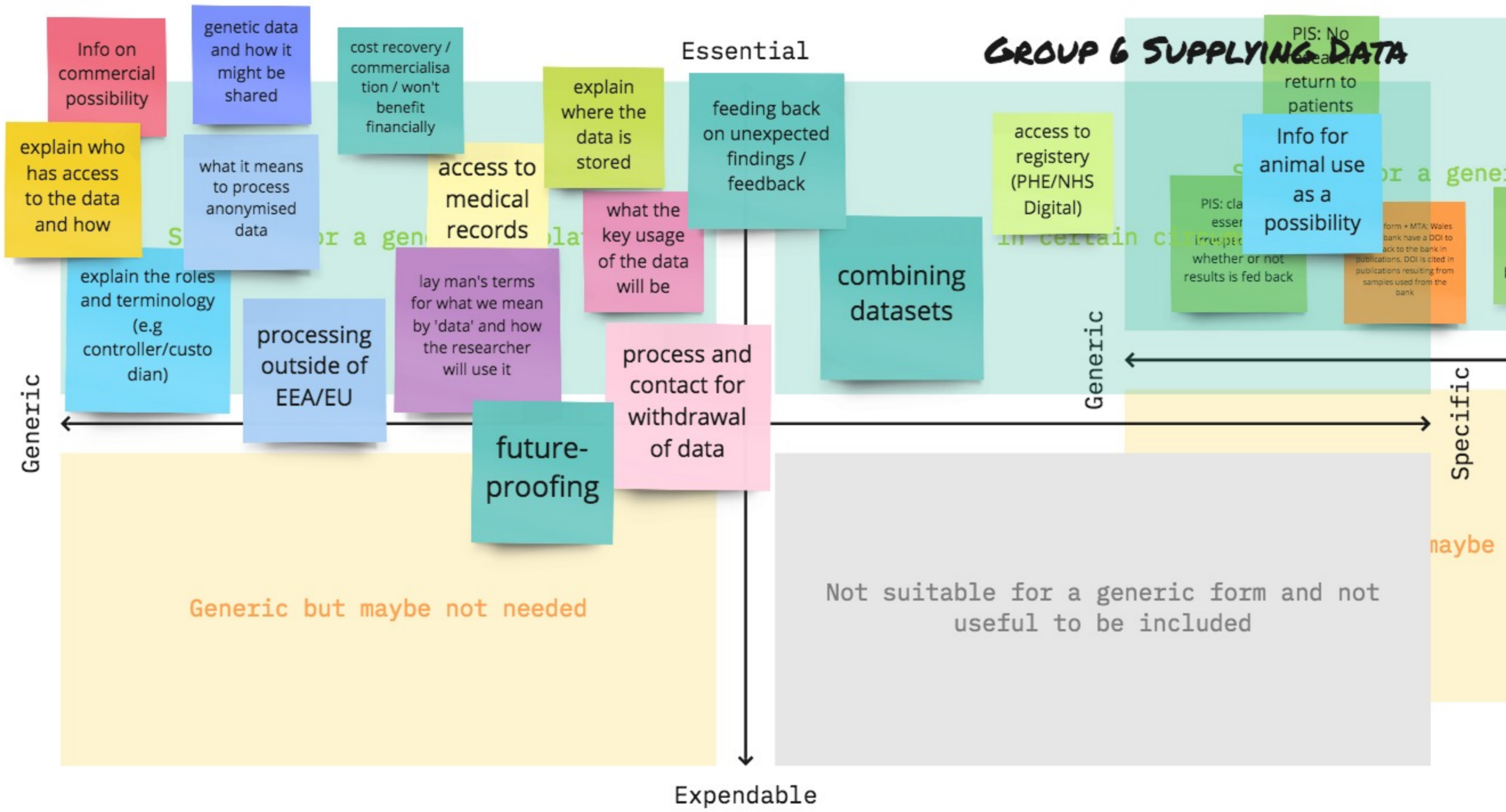
Comment: lack of consistency in acknowledging biobanks in publications

Variability between data could be an issue being fed back to the bank

Raw data being supplied back to bank to use as resource within the bank

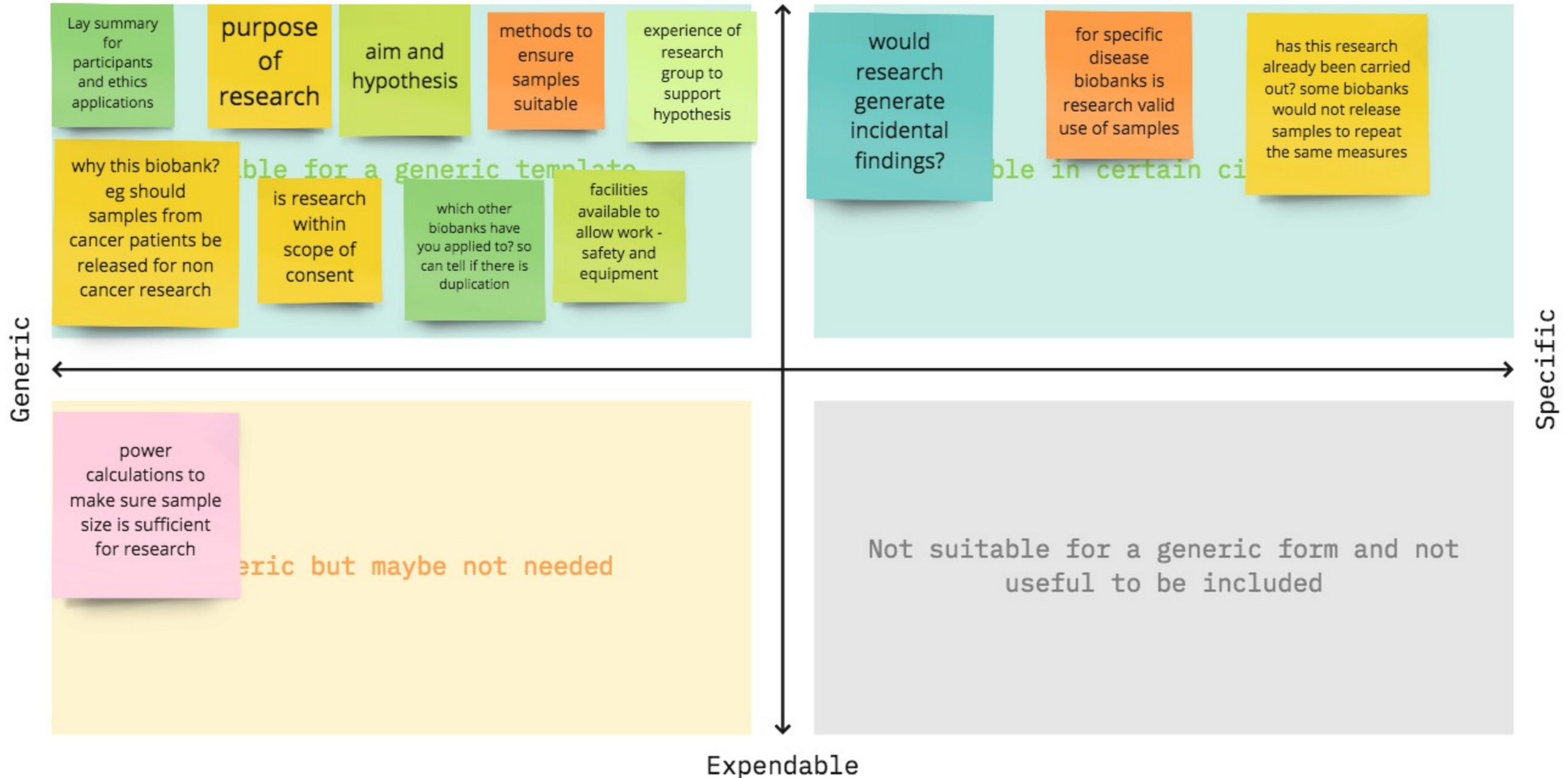
Specific

Expendable

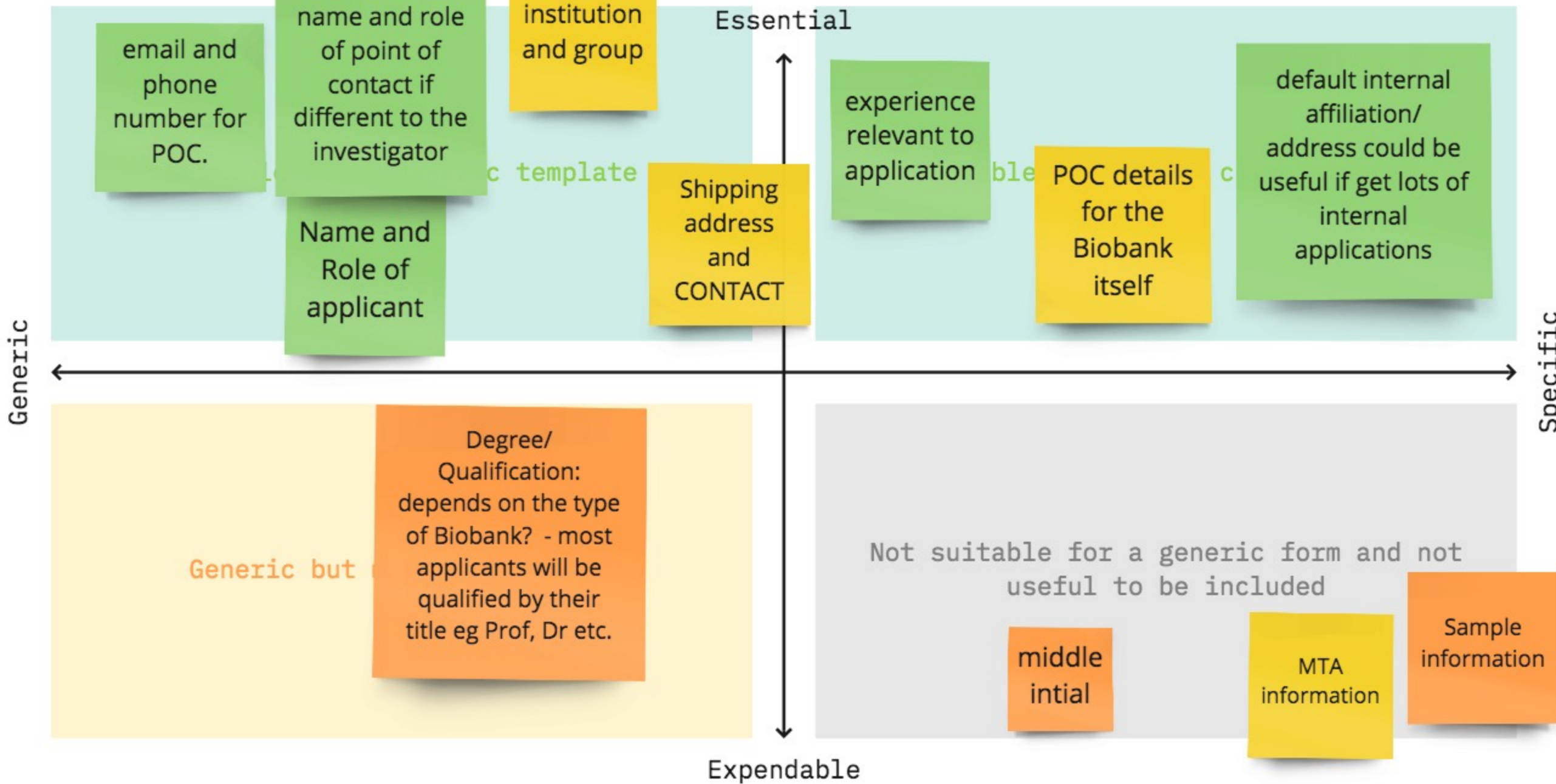


8. DESCRIPTION OF RESEARCH - ACCESS FORM

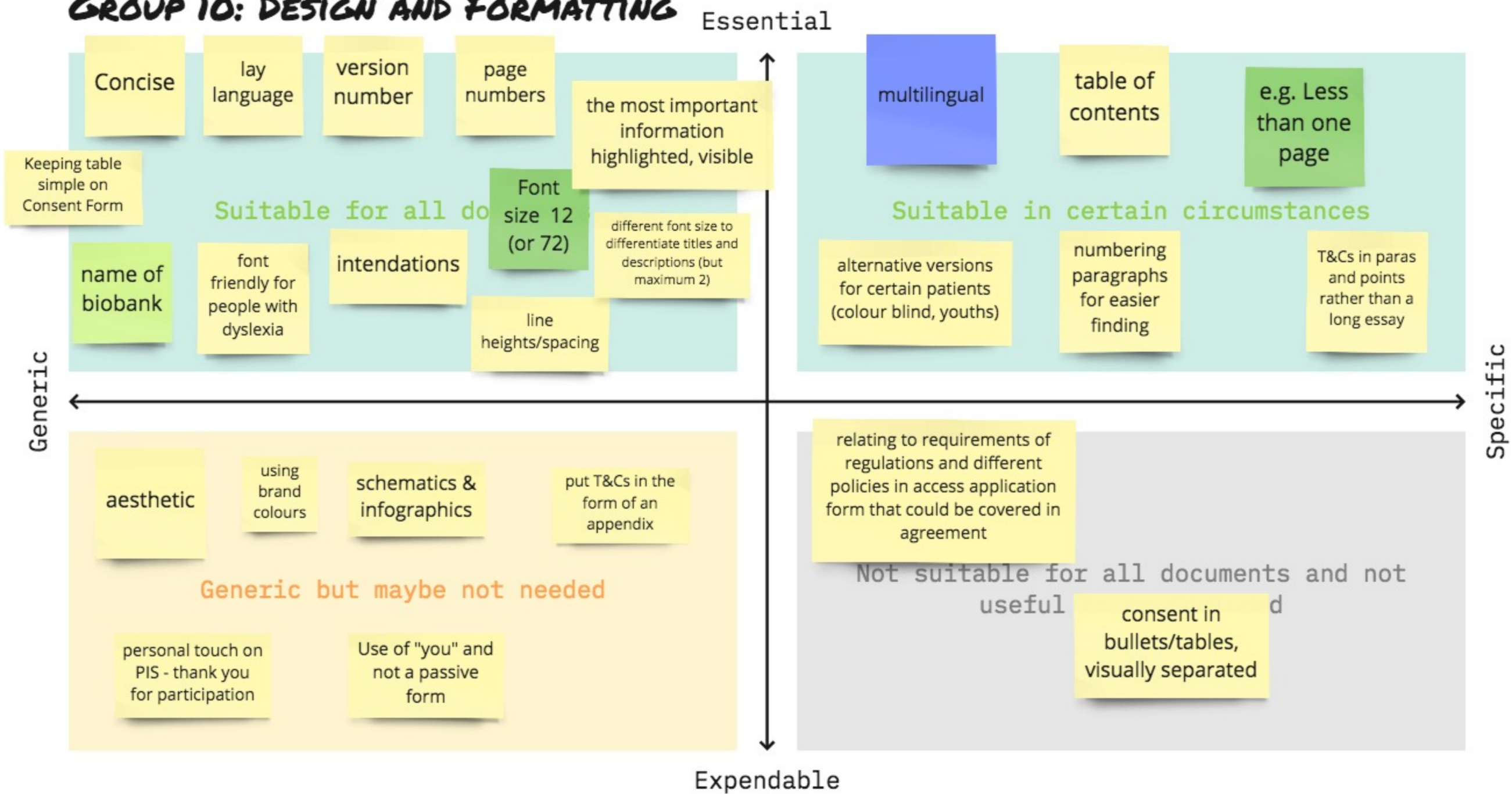
Essential



GROUP 9: DESCRIPTION OF TEAMS/SKILLS



GROUP 10: DESIGN AND FORMATTING



Essential

Expendable

Generic

Specific

Concise

lay language

version number

page numbers

the most important information highlighted, visible

Keeping table simple on Consent Form

Suitable for all documents

Font size 12 (or 72)

different font size to differentiate titles and descriptions (but maximum 2)

name of biobank

font friendly for people with dyslexia

intendations

line heights/spacing

multilingual

table of contents

e.g. Less than one page

Suitable in certain circumstances

alternative versions for certain patients (colour blind, youths)

numbering paragraphs for easier finding

T&Cs in paras and points rather than a long essay

aesthetic

using brand colours

schematics & infographics

put T&Cs in the form of an appendix

Generic but maybe not needed

personal touch on PIS - thank you for participation

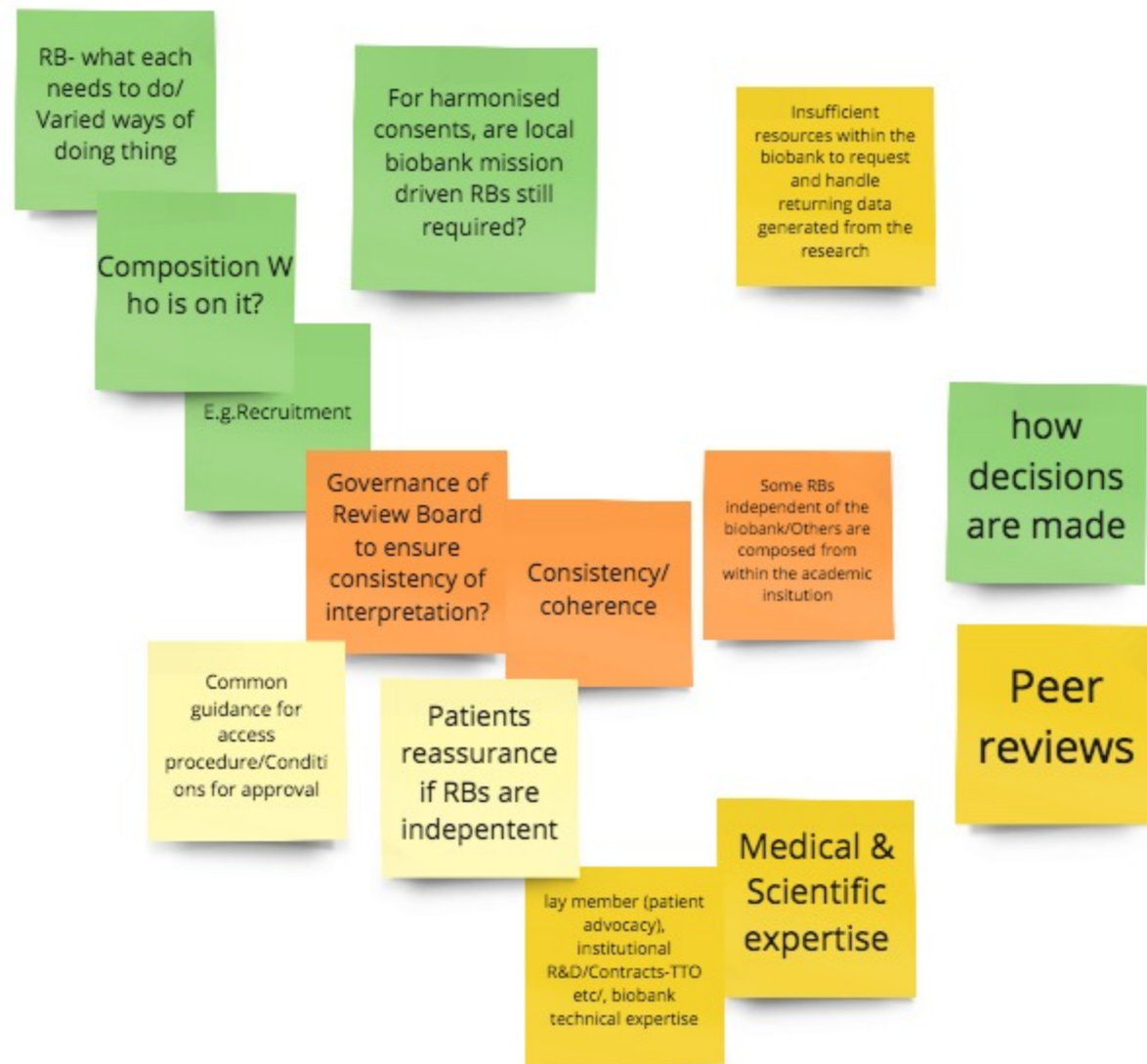
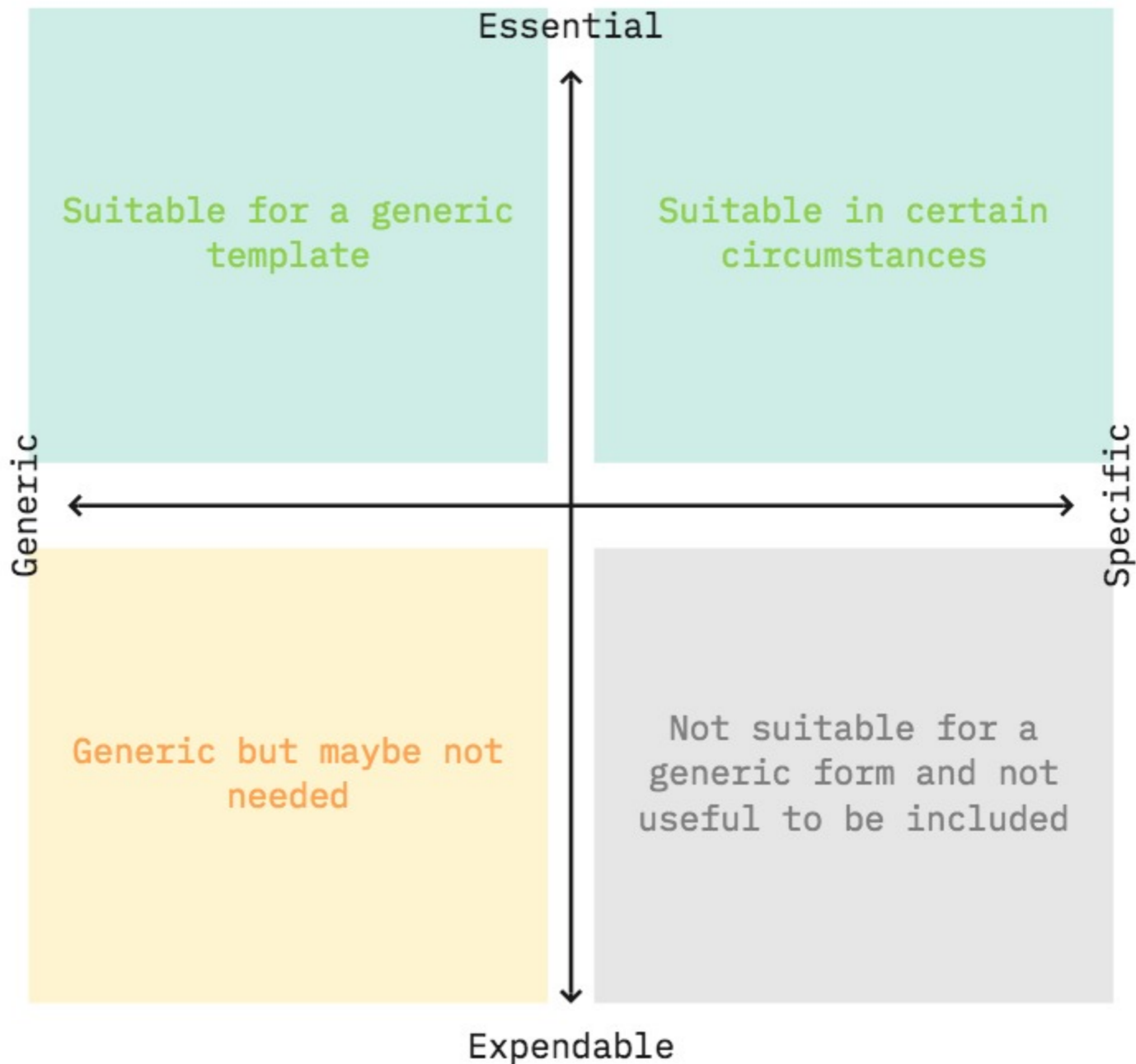
Use of "you" and not a passive form

relating to requirements of regulations and different policies in access application form that could be covered in agreement

Not suitable for all documents and not useful

consent in bullets/tables, visually separated

GROUP 4: REVIEW BOARD



GROUP 5. RESEARCH USE

